REMARKS

This is a request for continued examination (RCE). The foregoing amendment and following remarks are in response to the Final Office Action, mailed March 12, 2010. Reconsideration and continued examination of the above-referenced patent application is respectfully requested.

Claims 1-4, 6-8, 10-17, and 19-21 are pending. Claim 18 has been cancelled without prejudice. Claims 1, 6-8, 10, 11, 13, and 16 have been amended. New claims 19-21 have been added. Support for claim amendments and new claims may be found at, for example, paragraphs 26, 34, 35, and 75. No new matter has been introduced.

The Examiner objected to claim 18 under 37 C.F.R. 1.75(c) for failing to further limit the subject matter of a previous claim. Claim 18 has been cancelled without prejudice. Accordingly, Assignee respectfully submits that the Examiner's objection is therefore moot.

Claims 1-4, 6-8, and 10-17 stand rejected. Claims 1-4, 6-8, and 10-17 were rejected under 35 U.S.C. §112, ¶2 as being indefinite. Claims 1-3, 6, and 11 stand rejected under 35 U.S.C. §103(a) as being obvious given U.S. Patent Application Publication No. 2003/0208259 to Penhasi ("Penhasi") in view of a combination of U.S. Patent No. 6,562,939 to Farachi et al. ("Farachi"), "Study on the Synthesis and Biodegradation of Aliphatic Polyester," Chinese Chemical Letters Vol. 12, No. 7, Pp 589-592, 2001 by Zhu et al. ("Zhu"), and U.S. Patent No. 6,368,346 to Jadhav ("Jadhav"). Claims 1, 3-4, 8, 10, 12-15, and 17 stand rejected under 35 U.S.C. §103(a) as being obvious given U.S. Patent

Application Publication No. 2003/0211035 to Burns et al. ("Burns"). Claims 1 and 16 stand rejected under 35 U.S.C. §103(a) as being obvious given Burns in view of a combination of "Journal of Controlled Release 1991, 16:341-348" by Yoshioka et al. ("Yoshioka") and "Biodegradation 2002, 13:141-147" by Hoshino et al. ("Hoshino"). Claims 1 and 7 stand rejected under 35 U.S.C. §103(a) as being obvious given International Publication No. WO 94/21228 to Duan et al. ("Duan") in view of Farachi. These rejections are respectfully traversed.

In view of the following remarks, it is submitted that the claims pending in the application are novel and nonobvious and that the rejections are traversed. It is believed that this application is in condition for allowance. By this response, reconsideration of the present application is respectfully requested.

A. Claim rejections under 35 U.S.C. §112, ¶2

Claims 1-4, 6-8, and 10-17 stand rejected under 35 U.S.C. §112, ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, the Examiner states that the combination of terms "different drug delivery systems" and "one or more ... structures" in claim 1 rendered the claim indefinite because it was unclear whether one structure or multiple structures were implied by the claim. Assignee has amended the term "different drug delivery systems" to "*one or more* ... drug delivery systems" and respectfully submit that the scope of "drug delivery systems" is clearly defined. Accordingly, independent claim 1 is not indefinite. Assignee therefore respectfully submits that the rejection of independent claim 1 and claims 2-4, 6-8,

and 10-17 depending therefrom, either directly or indirectly (i.e., through claim dependencies), under 35 U.S.C. §112, ¶2 should be withdrawn.

B. Claim rejections under 35 U.S.C. §103

The Examiner is reminded that to successfully make a *prima facie* rejection under 35 USC § 103, the Examiner must show that Assignee's claimed subject matter would have been obvious to one of ordinary skill in the art pertinent to Assignee's claimed subject matter at the time it was made. *See*, KSR International, Co. v. Teleflex, Inc., US Supreme Court (decided April 30, 2007). Some of the factors to consider in this analysis include the differences between the applied documents and Assignee's claimed subject matter, along with the level of skill associated with one of ordinary skill in the art pertinent to Assignee's claimed subject matter at the time it was made. One way in which an Examiner may establish a *prima facie* case of unpatentability under 35 USC § 103 would be to show that three basic criteria have been met. First, the Examiner should show that the applied documents, alone or in combination, disclose or suggest every element of Assignee's claimed subject matter. Second, the Examiner should show that there is a reasonable expectation of success from the proposed combination. Finally, the Examiner should show that there was some suggestion or motivation, either in the applied documents themselves or in the knowledge generally available to one of ordinary skill in the art pertinent to the claimed subject matter at the relevant time, to modify the document(s) or to combine document teachings. The motivation or suggestion to make the proposed combination and the reasonable expectation of success should be found in the prior art, and should not be based on Assignee's disclosure. *See*, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed.

Cir. 1991); *See*, MPEP § 2142; 2143 - § 2143.03 (regarding decisions pertinent to each of these criteria). It is respectfully asserted that the Examiner has not met these standards.

Furthermore, on October 10, 2007, the USPTO published in the Federal Register its Examination Guidelines under 35 USC § 103 in view of the KSR decision, cited above. These guidelines contain a number of relevant points. In particular, the new Guidelines state that an Examiner must articulate a reason or rationale to support an obviousness rejection. Specifically, Examiner's must articulate findings as to the scope and content of the prior art to support the obviousness rejection being made. The Examiner should focus on the state of the art and not on impermissible hindsight (e.g., from inappropriate use of Assignee's disclosure). Specifically, Examiners need to account for all claim limitations in the rejections, either by indicating how each limitation is shown by the applied documents or by providing an explanation of how the document is legally relevant despite the limitation not being shown. Thus, Examiners must explain reasoning that provides a nexus between the factual findings and the legal conclusions of obviousness. It is respectfully asserted that the Examiner has not met these standards.

Claims 1-3, 6, and 11 - Penhasi in view of Farachi, Zhu, and Jadhav

The Examiner states that Penhasi "teaches a stent composed of a blend of elastomeric and non-elastomeric polymers along with a drug." [Office Action, P. 5.] The Examiner further states that Penhasi shows that the drug is incorporated in a polymer matrix. The Examiner also states that Penhasi does not show that the stent is molded and fails to show the molecular weight of polyethylene sebacate. However, the Examiner stated that Farachi shows that polyalkylene sebacates are "good for their mechanical

strength, desirable molecular weights, and degradability." [Office Action, P. 5.] The Examiner further states that Zhu shows "aliphatic polyesters are preferred among biodegradable polymers due to their better biodegradability properties and that this property depends upon their molecular weight." [Office Action, P. 5.] The Examiner also states that Jadhav shows "a polymeric stent that is taught to be molded into the desired shape." [Office Action, P. 6.] The Examiner further states that it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine Penhasi, Farachi, Zhu, and Jadhav in the direction of claims 1-3, 6, and 11.

Claim 1, as amended, recites:

> 1. A pharmaceutical composition, comprising:
> at least one pharmaceutically active ingredient;
> poly(ethylene sebacate); and
> wherein said pharmaceutical composition is in the form of one or more solid or liquid drug delivery systems, wherein said one or more solid or liquid drug delivery systems comprise one or more of the following structures: drug loaded microcapsules, nanoparticles, non-stent molded implants, coated granules, films, coated tablets, ophthalmic inserts, fibers, ligatures or sutures.

Penhasi appears to show an expandable polymeric stent. [Penhasi, para. 15.] Farachi appears to show a method for producing biodegradable aliphatic polyesters. [Farachi, Col. 1, lines 7-10.] Farachi appears to show a process for synthesizing poly(alkylene sebacates). [Farachi, Col. 2, lines 63-65.] Zhu appears to show synthesis of an aliphatic polyester and subsequent biodegradation of the aliphatic polyester was studied. [Zhu, P. 589, lines 30-33.] Jadhav appears to show a bio-compatible polymeric stent. [Jadhav, Col. 3, lines 42-50.]

Assignee notes that the Examiner appears to have cited Penhasi and Jadhav because claim 1 recites the limitation, "molded implants." However, Assignee notes that Penhasi and Jadhav merely show *stents*, not *molded implants*. Assignee further notes that

stents are not recited in claim 1. Assignee also notes that the specification for the present application distinguishes "molded implants" from "stents" in several locations. For example, paragraph 26 recites different drug delivery systems, "such as drug loaded microparticles, *molded implants*, coated granules, injectable sustained release particles, *stents*, ..." To clarify the scope of claim 1, however, "molded implants" has been amended to recite "non-stent molded implants." Assignee submits that the stents shown in Penhasi and Jadhav therefore fall outside the scope of claim 1. Moreover, Assignee further notes that the combination of Penhasi, Farachi, Zhu, and Jadhav fails to show poly(ethylene sebacate) and one or more drug delivery systems comprising a non-stent molded implant of poly(ethylene sebacate).

Assignee also notes that Farachi appears to show a process for synthesizing poly(*alkylene* sebacates) [see Col. 2, lines 63-65], not poly(*ethylene* sebacate), as is recited in claim 1. In the Office Action, the Examiner argues that Farachi "[exemplifies] polyethylene sebacate as a particular polyalklene sebacate (see column 4 lines 57-59; instant claim 2)." Assignee disagrees with the Examiner's argument that Farachi shows that polyethylene sebacate as a particular polyalklene sebacate. Specifically, Assignee has reviewed the section of Farachi referenced by the Examiner and notes that Farachi does not show that polyethylene sebacate is an example of a polyalklene sebacate.

Accordingly, claim 1 as amended distinguishes Penhasi in view of Farachi, Zhu, and Jadhav. Claims 2-4, 6-8, 10-17, and 19 depend, directly or indirectly (i.e., through claim dependencies) from claim 1 and therefore also distinguish Penhasi in view of Farachi, Zhu, and Jadhav for at least the same reasons as those discussed above with respect to claim 1.

Assignee notes that new claim 19 further distinguishes the cited documents. Specifically, claim 19 recites that the non-stent molded implant is formed by *melt molding*. As discussed above, the combination of Penhasi in view of Farachi, Zhu, and Jadhav fails to show a non-stent molding. The combination of the documents therefore also necessarily fails to show that the non-stent molded implant is formed by *melt molding*.

Claims 1, 3-4, 8, 10, 12-15, and 17 - Burns

Claims 1, 3-4, 8, 10, 12-15, and 17 stand rejected under 35 U.S.C. §103(a) as being obvious given Burns. The Examiner states that Burns shows "microspheres composed of polymers that are envisioned for biomedical applications." [Office Action, P. 6.] The Examiner also states that Burns shows microparticles "envisioned for controlled (sustained) release" and that the microparticles are suspended in gel. The Examiner further states that it would have been obvious to a person of ordinary skill in the art at the time of the invention to utilize polyethylene sebacate in bioactive microparticles. [Office Action, P. 8] The Examiner also states that claim 13 is a product-by-process claim and that same microparticles structure of claim 13 is shown in Burns even if the process was different.

Although Assignee disagrees with the Examiner's argument that Burns shows the same microparticles structure as that shown in claim 1, Assignee has deleted the term "microparticles" from claim 1 and added new independent claim 20 to recite the microparticles structure. Accordingly, Assignee respectfully submits that claim 1 therefore distinguishes Burns because Burns fails to show any of the other structures recited in claim 1. Accordingly, claims 1, 3-4, 8, 10, 12, 15, and 17 therefore also distinguish Burns.

Moreover, new claims 20 and 21 also distinguish Burns. Specifically, new claim 20 recites one or more solid or liquid drug delivery systems comprising at least drug loaded *microparticles produced by preparation of an oil/water suspension system utilizing polymer microparticles.* Burns appears to show that polymeric microspheres are prepared from monomers, not *polymer microparticles*, as is recited in claim 20. Moreover, the Burns appears to show that the monomers are dispersed and then dissolved within an emulsifying solution followed by solvent evaporation, electrostatically controlled extrusion, and injection into an emulsifying solution followed by solvent evaporation to produce the polymers. [Burns, para. 6.] Burns does not, however, show that drug loaded microparticles are produced by preparation on an oil/water suspension system.

Accordingly, new claims 20 and 21, depending therefrom, distinguish Burns.

Claims 1 and 16 – Burns in view of Yoshioka and Hoshino

Claims 1 and 16 stand rejected under 35 U.S.C. §103(a) as being obvious given Burns in view of a combination of Yoshioka and Hoshino. The Examiner states that Burns makes obvious microparticles compose of linear aliphatic polyester, but does not show the presence of a lipase in the microparticles. [Office Action, P. 8.] However, the Examiner states that Yoshioka shows the inclusion of an agent in a polymeric drug delivery system to hydrolyze the polymer and allow control of degradation rate of the polymer and subsequent rate of drug release. [Office Action, P. 8.] The Examiner also states that Hoshino shows that lipases were know to degrade a linear aliphatic polyester of the same form as polyethylene sebacate. [Office Action, P. 9.] Examiner further states that it would have

been obvious to a person of ordinary skill in the art at the time of the invention to combine Burns with Yoshioka and Hoshino in the direction of claims 1 and 16.

With respect to claim 1, Assignee notes that Burns fails to disclose the claimed structures for drug delivery systems, as discussed above. Yoshioka and Hoshino both appear to show studies of biodegradable systems. However, neither Yoshioka nor Hoshino, alone or in combination with Burns, show any of the drug delivery structures recited in claim 1.

Claim 16 depends from claim 1 and recites "*drug delivery systems comprise lipase* capable of modifying release of said pharmaceutically active ingredient."

Yoshioka appears to show a study of polymer hydrolysis in base-loaded poly films. However, Yoshioka does not show use of a lipase in the study. [Yoshioka, P. 341.] Hoshino appears to show a study of lipases for their degradation efficiency of aliphatic polyester films, such as poly (L-lactide) (PLA). [Hoshino, Abstract.] However, Assignee notes that claim 1, from which claim 16 depends, recites use of *poly(ethylene sebacate)*, not *PLA*. Moreover, paragraph 18 of the present application distinguishes PLA, listing disadvantages of PLA polyesters.

Accordingly, claims 1 and 16 distinguish Burns in view of Yoshioka and Hoshino .

Claims 1 and 7 – Duan in view of Farachi

Claims 1 and 7 stand rejected under 35 U.S.C. §103(a) as being obvious given Duan in view of Farachi. The Examiner states that Duan shows a composition composed of particulate (granule) drug and a dispersing agent that is a compound comprising a chain of diol/diacid condensate and a propellant. [Office Action, P. 9.] The Examiner also states

that Duan shows that the particulate drug can be coasted with the dispersant. [Office Action, P. 10.] The Examiner further notes that Duan does not show that the diacid is sebacic acid. However, the Examiner states that Farachi shows biodegradable polyesters and polyalkylene sebacates. The Examiner further states that it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine Duan and Farachi in the direction of claims 1 and 7.

As discussed above, claims 1 and 7 distinguish Farachi. Duan does not make up for the deficiencies of Farachi. For example, Duan appears to show an *aerosol* drug formulation where the drug is dispersed through the air, e.g., a gas. [Duan, P. 1, lines 10-12.] Claim 1, on the other hand, recites a pharmaceutical composition that is in the form of one or more *solid or liquid drug delivery systems*. Assignee notes that the *aerosol* drug formulation of Duan is not a *solid or liquid drug delivery system*.

Accordingly, claim 1 and claim 7, depending therefrom, therefore distinguish Duan and Farachi.

Even under the PTO guidelines released after the KSR decision, the Examiner should explain how the applied documents are legally relevant despite limitations not being shown. Accordingly, Assignee respectfully submits that claims 1-4, 6-8, and 10-17 are not made obvious by the applied documents and requests withdrawal of the rejection of claims 1-4, 6-8, and 10-17 under 35 USC § 103 (a).

Failure of the Assignee to respond to a position taken by the Examiner is not an indication of acceptance or acquiescence of the Examiner's position. It is believed that the

Examiner's positions are rendered moot by the foregoing and, therefore, it is not necessary to respond to every position taken by the Examiner with which Assignee does not agree in this or other correspondence. Instead, it is believed that the foregoing addresses the issues raised by the Examiner and that the present claims are in condition for allowance.

CONCLUSION

The foregoing is submitted as a full and complete response to the Final Office Action mailed March 12, 2010. In view of the foregoing amendment and remarks, Assignee respectfully submits that pending claims are in condition for allowance and a notification of such allowance is respectfully requested.

If the Examiner believes that there are any remaining informalities that can be corrected by an Examiner's amendment, a telephone call to the undersigned at 503.439.6500 is respectfully solicited.

In the event there are any errors with respect to the fees for this response or any other papers related to this response, the Director is hereby given permission to charge any shortages and credit any overcharges of any fees required for this submission to Deposit Account No. 50-3130.

Respectfully submitted,

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